

REMARKS

Reconsideration of the application as amended is respectfully requested.

Pursuant to 37 C.F.R. § 1.136(a), Applicants hereby request a three month extension of the term for reply set by the August 28, 2001 Office Action, i.e., up to and including February 4, 2002. Enclosed herewith is a check for \$820 which includes the fee for a three month extension of time to respond to an official action for a small entity (\$460) as well as the fee for a six additional independent claims (\$252) and twelve additional claims in excess of twenty for a small entity (\$108). The Commissioner is authorized to charge any additional fees or any fee for further extensions of time to Deposit Account No. 50-0320.

Claims 7-10, 12-14, 16-17, 19-20, 22-44 are pending. Claims 3, 5, 6, 9, 11, 15 and 21 are cancelled, claims 7-8, 10, 12, 16, 17, 19, 20, and 22-24 are amended and new claims 26-44 are added without prejudice. Support for the amended claims and new claims can be found throughout the specification and in the original claims as filed.

Claims 3, 5-7 and 19-25 are rejected under 35 U.S.C. §112 second paragraph as being allegedly indefinite. The rejection is traversed.

Claim 3 is cancelled without prejudice thereby obviating the rejection.

Claim 5 is cancelled without prejudice rendering the rejection moot.

Claims 8 and 20 are amended to delete the recitation "where appropriate" thereby obviating the rejection.

Claims 9 and 21 are cancelled without prejudice thereby rendering this rejection moot.

Claim 10 is amended to delete the phrase "nucleic acid like" thereby obviating the rejection.

Claim 11 is cancelled without prejudice rendering the rejection moot.

Claim 12 is amended to include positive active process steps relating back to the preamble thereby obviating the rejection.

Claim 15 is cancelled without prejudice thereby rendering the rejection moot.

Claims 3, 5-11 and 19-25 are rejected under U.S.C. §101 as being allegedly directed to non-statutory subject matter. The rejection is traversed. Claims 3, 5, 6, 9, 11, 15 and 21 are cancelled and claims 7-8, 10-12, 16, 17, 19, 20, and 22-24 are amended thereby rendering the rejection moot.

Claims 3, 5-17 and 19-25 are rejected under Section 112, first paragraph, as containing subject matter allegedly not described in the specification in such a way as to reasonably convey to a skilled artisan that Applicants had possession of the claimed subject matter at the time the application was filed. It is alleged in the Office Action that the claimed invention represents a broad genus for which a representative number of species of such a genus must be disclosed to fulfil the description requirement of 112, first paragraph and that absent of written description disclosing a representative number of the species of the isolated nucleic acids of SEQ ID NOS 1 and 3-5, or to methods of using such a broad genus, the specification allegedly fails to show that the Applicant was in fact, "in possession of the claimed invention" at the time that the application was filed.

The allegations are without merit as possession clearly existed.

The lead case on the written description requirement is *In re Edwards*, 568 F.2d 1349 (C.C.P.A. 1970). The application of that case by the Federal Circuit is the state of the law on the issue. According to *Edwards*, the function of the written description requirement is to:

[E]nsure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; to comply with the description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.

(*Id.* at 1351-52) (emphasis added).

Thus, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by a skilled artisan. Such knowledge can be established by reference to patents and publications available to the public prior to the filing date of the application.

Applying the law to the instant facts, it is clear possession did exist at the time of filing. The present invention is directed to, *inter alia*, an isolated nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule comprises a shortened sequence as compared to that of SEQ ID No. 1 and a method of detecting the presence or absence of bacteria using a kit containing the isolated nucleic acid molecules.

Applicants respectfully submit that a skilled artisan would readily understand the method for detecting the presence or absence of bacteria using nucleic acid molecules that differ from the nucleic acid as claimed for the detection of bacteria of the genus *Pseudomonas*.

Further, a skilled artisan, reading the instant specification, would readily understand that possession existed because this same artisan would know the procedures for the specific detection of bacteria whether the nucleic acid sequences were the same or different to the nucleic acid sequence as claimed.

Consequently, reconsideration and withdrawal of the rejection are requested.

Claims 5 and 9 are rejected under U.S.C. §102(b) as being allegedly anticipated by X15400. The rejection is traversed.

This rejection is moot since claims 5 and 9 are canceled and new claims are submitted. The cited reference does not anticipate the instant invention.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. See *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. See *Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. See *In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, the DNA sequence of accession No. X15400 relied upon by the Office Action does not disclose, suggest or enable the Applicants' invention.

The assertion of the Office Action that accession No. X15400 allegedly teaches a sequence that possesses at least 10 consecutive sequences of SEQ ID No.3 is irrelevant because accession number X15400, a DNA sequence of a *Drosophila* glass gene encoding a zinc finger protein does not enable the presently claimed invention.

Therefore, accession No. X15400 is not proper evidence of anticipation (because a skilled artisan, who is aware of the DNA sequence of accession No. X15400, would not have been in possession of the instantly claimed invention) the Section 102 rejections cannot stand.

Claims 6-17 and 19-25 are rejected under 35 U. S. C. §103(a) as being allegedly unpatentable over accession No. Y00432 or accession No. X15400. The rejections will be addressed collectively and are respectfully traversed.

The Examiner is reminded of the fact that a claimed species or subgenus is allegedly encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness, *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d, 1552 (Fed. Cir. 1994). Some motivation to select the claimed species or subgenus must be taught by the prior art. See, e.g., *Deuel*, 51 F.3d at 1558-59, 34 USPQ2d at 1215 ("No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared."); *Baird*, 16 F.3d at 382-83, 29 USPQ2d at 1552; *Bell*, 991 F.2d at 784, 26 USPQ2d at 1531 ("Absent anything in the cited prior art suggesting which of the 1036 possible sequences suggested by Rinderknecht corresponds to the IGF gene, the PTO has not met its burden of establishing that the prior art would have suggested the claimed sequences.") (see MPEP 2144.08).

In conclusion, there is no teaching or suggestion in accession Nos. Y00432 or X15400 that would motivate a skilled artisan to isolate and utilize any of the isolated nucleic acid molecules as claimed herein or incorporate them into the kit as claimed.

Therefore accession Nos. Y00432 or X15400 do not teach, suggest, disclose or motivate a skilled artisan to practice the instantly claimed invention.


Applicants wish to note that included herewith is a change of correspondence address for this application.

In view of the amendments and remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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VERSION TO SHOW CHANGES MADE

IN THE CLAIMS:

7. (Amended) [A] The isolated nucleic acid [molecule] sequence according to claim [3] 30, wherein the nucleic acid [molecule] sequence is single-stranded or double-stranded.

8. (Amended) [A] The isolated nucleic acid molecule according to claim [3] 30, wherein the nucleic acid [molecule] sequence is present

(iv) as DNA or

(v) as RNA corresponding to (i) or

(vi) as PNA

[the nucleic acid molecule where appropriate having been modified in a manner known *per se* for analytical detection processes, especially those based on hybridisation and/or amplification.]

10. (Amended) [A] The isolated nucleic acid molecule according to claim 8, wherein the nucleic acid [molecule] sequence has been modified or labelled or additionally modified or labelled in such a manner that it comprises, in a manner known *per se* for analytical detection processes, one or more radioactive groups, coloured groups, fluorescent groups, groups for immobilisation on a solid phase or groups for an indirect or direct reaction[, or otherwise modifying or modified groups of nucleic-acid-like structure].

12. (Amended) A method of detecting the presence or absence of bacteria comprising the [step] steps of : (i) using a kit according to claim 11; (ii) carrying out nucleic acid hybridisation or nucleic acid amplification or nucleic acid hybridization plus amplification [for detection of] and detecting the presence or absence of bacteria belonging to a group of bacteria of the *Pseudomonas* genus.

16. (Amended) The method according to claim [15] 12, wherein[, as] said nucleic acid amplification[, a] is carried out by a polymerase chain reaction [is carried out].

17. (Amended) The method according to claim 12, wherein the detection is carried out by distinguishing the to-be-detected bacteria from not-to-be-detected bacteria on the basis of differences in the genomic DNA or RNA in at [at] least one nucleotide position in the region of a nucleic acid [molecule] sequence according to claim [3] 30.

19. (Amended) [A] An isolated nucleic acid molecule according to claim 6, wherein the nucleic acid [molecule] sequence is from 15 to 30, nucleotides long.

20. (Amended) [A] An isolated nucleic acid molecule according to claim 8, wherein the nucleic acid molecule is present

- (iv) as DNA or
- (v) as RNA corresponding to (i) or
- (vi) as PNA[,

the nucleic acid molecule where appropriate having been modified in a manner known *per se* for analytical detection processes bases on hybridisation or amplification.]

22. (Amended) [A] An isolated nucleic acid molecule according to claim [3] 30, wherein the nucleic acid [molecule] sequence has been modified in such a manner that up to 20 % of the nucleotides of at least 10 contiguous nucleotides of its nucleotide chain have been replaced by nucleotides that do not occur naturally in bacteria.

23. (Amended) [A] An isolated nucleic acid molecule according to claim 10, wherein the nucleic acid [molecule] sequence has been modified or labelled or additionally modified or labelled in such a manner that it comprises, in a manner know *per se* for analytical detection processes, one or more radioactive groups, coloured groups, fluorescent groups, groups for immobilisation on a solid phase or groups for an indirect or direct enzymatic reaction.

24. (Amended) [A] An isolated nucleic acid molecule according to claim 10, wherein the nucleic acid [molecule] sequence has been modified or labelled or additionally modified or labelled in such a manner that it comprises, in a manner know *per se* for analytical detection processes, one or more groups for an indirect or direct reaction using antibodies, antigens, enzymes or substances having an affinity for enzymes or enzyme complexes.